Food and Drug Administration, HHS

- (3) Each tablet contains 250 milligrams (mg) sulfachlorpyridazine.
- (b) *Sponsor*. See No. 000010 in §510.600(c) of this chapter.
- (c) Related tolerances. See §556.630 of this chapter.
- (d) Conditions of use. It is used as follows:
- (1) Calves—(i) Amount. Administer 30 to 45 mg sulfachlorpyridazine powder per pound (/lb) of body weight per day in milk or milk replacer, or in a bolus, in divided doses twice daily for 1 to 5 days.
- (ii) *Indications for use*. For the treatment of diarrhea caused or complicated by *Escherichia coli* (colibacillosis).
- (iii) Limitations. Treated ruminating calves must not be slaughtered for food during treatment or for 7 days after the last treatment. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for yeal.
- (2) Swine—(i) Amount. Administer 20 to 35 mg/lb body weight per day, in divided doses twice daily for 1 to 5 days:
 - (A) In drinking water or
- (B) For individual treatment, in an oral suspension containing 50 mg per milliliter.
- (ii) *Indications for use*. For the treatment of diarrhea caused or complicated by *E. coli* (colibacillosis).
- (iii) *Limitations*. Treated swine must not be slaughtered for food during treatment or for 4 days after the last treatment.
- (3) Dogs—(i) Amount. Administer tablets orally at 500 mg per 10 to 15 lb of body weight daily, in two or three divided doses.
- (ii) Indications for use. As an aid in the treatment of infectious tracheobronchitis and infections caused by E. coli, and in the treatment of infections caused by other Grampositive and Gram-negative organisms that are susceptible to sulfonamide therapy.
- (iii) *Limitations*. Federal law restricts this drug to use only by or on the order of a licensed veterinarian.

[75 FR 10166, Mar. 5, 2010]

§ 520.2215 Sulfadiazine/pyrimethamine suspension.

- (a) Specifications. Each milliliter (mL) of suspension contains 250 milligrams (mg) sulfadiazine (as the sodium salt) and 12.5 mg pyrimethamine.
- (b) *Sponsor*. See No. 055246 in §510.600(c) of this chapter.
- (c) Conditions of use in horses—(1) Amount. Administer orally 20 mg sulfadiazine per kilogram (kg) body weight and 1 mg/kg pyrimethamine daily.
- (2) Indications for use. For the treatment of equine protozoal myeloencephalitis (EPM) caused by Sarcocystis neurona.
- (3) Limitations. Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.
- [69 FR 70054, Dec. 2, 2004, as amended at 73 FR 53686, Sept. 17, 2008; 75 FR 69586, Nov. 15, 2010]

§ 520.2218 Sulfamerazine, sulfamethazine, and sulfaquinoxaline powder.

- (a) Specifications. Each 195-gram (g) packet of powder contains 78 g sulfamerazine, 78 g sulfamethazine, and 39 g sulfaquinoxaline.
- (b) Sponsor. See No. 046573 in $\S510.600$ (c) of this chapter.
- (c) Related tolerances. See §§ 556.670 and 556.685 of this chapter.
- (d) Conditions of use—(1) Chickens—(1) Amounts and indications for use—(A) As an aid in the control of coccidiosis caused by Eimeria tenella and E. necatrix susceptible to sulfamerazine, sulfamethazine, and sulfaquinoxaline: provide medicated water (0.4 percent solution) for 2 to 3 days, then plain water for 3 days, then medicated water (0.25 percent solution) for 2 days. If bloody droppings appear, repeat at 0.25 percent level for 2 more days. Do not change litter.
- (B) As an aid in the control of acute fowl cholera caused by *Pasteurella multocida* susceptible to sulfamerazine, sulfamethazine, and sulfaquinoxaline: provide medicated water (0.4 percent solution) for 2 to 3 days. If disease recurs, repeat treatment.
- (ii) Limitations. Make fresh solution daily. Do not treat chickens within 14 days of slaughter for food. Do not

§ 520.2220

medicate chickens producing eggs for human consumption.

- (2) Turkeys—(i) Amounts and indications for use—(A) As an aid in the control of coccidiosis caused by Eimeria meleagrimits and E. adenoeides susceptible to sulfamerazine, sulfamethazine, and sulfaquinoxaline: provide medicated water (0.25 percent solution) for 2 days, then plain water for 3 days, then medicated water (0.25 percent solution) for 2 days, then plain water for 3 days, then medicated water (0.25 percent solution) for 2 days. Repeat if necessary. Do not change litter.
- (B) As an aid in the control of acute fowl cholera caused by *Pasteurella multocida* susceptible to sulfamerazine, sulfamethazine, and sulfaquinoxaline: provide medicated water (0.4 percent solution) for 2 to 3 days. If disease recurs, repeat treatment.
- (ii) Limitations. Make fresh solution daily. Do not treat turkeys within 14 days of slaughter for food. Do not medicate turkeys producing eggs for human consumption.

[71 FR 13001, Mar. 14, 2006]

§520.2220 Sulfadimethoxine oral dosage forms.

§ 520.2220a Sulfadimethoxine oral solution and soluble powder.

- (a) *Approvals*. (1) For oral solution containing 12.5 percent (3.75 grams per ounce) sulfadimethoxine, see Nos. 000010, 000069, 000859, 054925, and 057561 in \$510.600(c).
- (2) For soluble powder, each 107 grams contain the equivalent of 94.6 grams of sulfadimethoxine (as the sodium salt); see Nos. 000069, 054925, 057561, 058829, 061623, and 066104 in §510.600(c) of this chapter.
- (b) Special considerations. Federal law prohibits the extralabel use of this product in lactating dairy cattle.
- (c) Related tolerances. See §556.640 of this chapter.
- (d) Conditions of use. The oral solution is administered as a cattle drench or diluted as directed to prepare drinking water. The powder is used to prepare a drench or drinking water. The concentrations and uses of the various solutions are as follows:

- (1) Broiler and replacement chickens only—(i) Amount. 1.875 (0.05 percent) grams per gallon.
- (ii) *Indications for use*. Treatment of disease outbreaks of coccidiosis, fowl cholera, and infectious coryza.
- (iii) Limitations. Administer for 6 consecutive days; do not administer to chickens over 16 weeks of age; as sole source of drinking water and sulfonamide medication; as sulfadimethoxine solution or sulfadimethoxine soluble sodium salt; withdraw 5 days before slaughter.
- (2) Meat-producing turkeys only—(i) Amount. 0.938 (0.025 percent) grams per gallon.
- (ii) Indications for use. Treatment of disease outbreaks of coccidiosis and fowl cholera.
- (iii) Limitations. Administer for 6 consecutive days; do not administer to turkeys over 24 weeks of age; as sole source of drinking water and sulfonamide medication; as sulfadimethoxine solution or sulfadimethoxine soluble sodium salt; withdraw 5 days before slaughter.
- (3) Dairy calves, dairy heifers, and beef cattle only—(i) Amount. 1.18 to 2.36 (0.031 to 0.062 percent) grams per gallon.
- (ii) Indications for use. For the treatment of shipping fever complex and bacterial pneumonia associated with Pasteurella spp. sensitive to sulfadimethoxine; and calf diphtheria and foot rot associated with Fusobacterium necrophorum (Sphaerophorus necrophorus) sensitive to sulfadimethoxine.
- (iii) Administer 2.5 grams per 100 pounds of body weight for first day, then 1.25 grams per 100 pounds of body weight per day for the next 4 consecutive days; in drinking water or drench; available as a sulfadimethoxine soluble percent powder ora. 12.5 sulfadimethoxine sodium solution (3.75 grams sulfadimethoxine per fluid ounce); if no improvement within 2 to 3 days, reevaluate diagnosis; do not treat beyond 5 days; withdraw 7 days before slaughter. A withdrawal period has not been established for this product in